DEC 3 0 2003

K033256

Appendix F

510(k) Premarket Notification Summary of Safety and Effectiveness Information	*Athena Pelvic Muscle Trainer II* *October 6, 2003*

1. Device Name
   Trade Name: : Athena Pelvic Muscle Trainer II
   Common Names: : Athena Pelvic Muscle Trainer II
   Classification Name: Stimulator, Electrical, Non-Implantable, for Incontinence

2. Establishment Name & Registration Number:

   Name: Athena Feminine Technologies

   Number: none

3. Classification:
   Title 21, Code of Federal Regulations,
   §Sec. 876.5320 ProCode: KPI

4. Guidance Documents, Performance Standards and Special Controls:
   At the present time, the following guidance documents are in effect for this device:

   Guidance on the Content and Organization of a Premarket Notification.

5. Equivalent Device(s): Utah Medical, Liberty PFS-200 System (K960496), Athena Pelvic Muscle Trainer (K023905)

6. Applicant/Sponsor Name / Address:
   Athena Feminine Technologies
   179 Moraga Way
   Orinda, CA 94563
   (925) 254-6090

7. Company Contact: George Sarkis, CEO
   Athena Feminine Technologies
   179 Moraga Way
   Orinda, CA 94563
   (925) 254-6090

8. Submission Correspondent: Barbara Sarkis, CIO
   Athena Feminine Technologies
   179 Moraga Way
   Orinda, CA 94563
   (925) 254-6090

9. Description of the Device and Indications for Use:

Description of the Device: The Athena Pelvic Muscle Trainer is a vaginal two electrode stimulation probe operated through a FM remote control device. The probe is stored in a cradle on the side of the remote control and is activated upon removal from the cradle.

Indications for use: The Athena Pelvic Muscle Trainer is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2003

Ms. Barbara Sarkis
Chief Information Officer
Athena Feminine Technologies, Inc.
179 Moraga Way
ORINDA CA 94563

Re: K033256
Trade/Device Name: Athena Pelvic Muscle Trainer II
Regulation Number: 21 CFR §876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: 78 KPI
Dated: October 6, 2003
Received: October 10, 2003

Dear Ms. Sarkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER: K033256

DEVICE NAME: ***Athena Pelvic Muscle Trainer II***

INDICATIONS FOR USE:

The **Athena Pelvic Muscle Trainer** is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** _____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033256